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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,407	12/08/2006	Takumi Teratani	701053	2167

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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,407	TERATANI ET AL.	
	Examiner	Art Unit	
	QUANG NGUYEN, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30 and 32-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30 and 32-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-30 and 32-34 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-7 and 21, drawn to a rat embryonic stem cell having recited properties (a)-(j) in claim 1, a culture kit comprising the same rat embryonic stem cell or a rat embryonic stem cell generated by the recited process in claim 2 (product-by-process claims).

Group II, claims 8-13, drawn to a method for producing a rat embryonic stem cell having the steps recited in claim 8.

Group III, claims 14-18, drawn to a subculture method of rat embryonic stem cells having the steps recited in claim 14.

Group IV, claims 19-20 and 22-23, drawn to a culture medium for a rat embryonic stem cell and a kit comprising the same.

Group V, claims 24-25, drawn a differentiation induction method of a rat embryonic stem cell having recited properties (a)-(j).

Group VI, claim 26, drawn to a differentiated cell obtained from the induced differentiation of a rat embryonic stem cell having recited properties (a)-(j).

Group VII, claim 27, drawn to a cDNA library, a genomic library or a cell extract derived from a rat embryonic stem cell having recited properties (a)-(j).

Group VIII, claims 28-29, drawn to a screening method of a differentiation inducer or a substance acting on the differentiation induction of a rat embryonic stem cell having recited properties (a)-(j).

Group IX, claims 30 and 32, drawn to a method for producing a genetically modified rat using a rat embryonic stem cell having recited properties (a)-(j).

Group X, claims 33-34, drawn to a genetically modified rat produced by the method of claim 32.

The technical feature linking Groups I-X appears to be that they all relate to a rat embryonic stem cell and particularly a rat embryonic stem cell having properties (a)-(j) as recited in claim 1.

The inventions listed as Groups I-X do not related to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
(1) A product and a process specifically adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specifically adapted for the manufacture of the said product, and a use of said product; or
(4) A process and an apparatus or means specifically adapted for the manufacture of the said product; or
(5) A product, a process specifically adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process."

Furthermore, according to the PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed

inventions. The "Instructions Concerning Unity of Invention" (MPEP, Administrative Instructions Under the PCT, Annex B, Part 1 (b) state, "The expression of 'special technical features' is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.". Thus, unity of invention exists only when the shared same or corresponding technical features is a contribution over the art. Administrative Instructions Under the PCT, Annex B state, If…an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no linkage remaining, an objection of lack of unity a *posteriori* (that is, arising only after assessment of the prior art) may be raised.

However at the effective filing date of the present application, Loring (US 2002/0188963; IDS) already reported the isolation and characterization of rat ES cells that are at least pluripotent, positive for alkaline phophatase, SSEA-1 markers, forming embryoid bodies under certain conditions, as well as having ability to produce a chimeric rat (see at least the abstract and examples 3-6); and these rat ES cells have substantially the same properties as those of a rat embryonic stem cell as claimed. Additionally, Vassilieva et al (Experimental cell Res. 258:361-373, 2000; IDS) also reported the establishment of pluripotent, and stable rat embryonic stem like cell lines that express SSEA-1 and Oct-4 (see at least the abstract) that share many properties as those of a rat embryonic stem cell as claimed.

Therefore, the technical feature linking the inventions of Groups I-X does not constitute a special technical feature a defined by PCT Rule 13.2, as it does not differentiate the claimed subject matter a whole over the prior art. Since according to Rule 13.2 PCT the presence of such a common or corresponding special technical feature is an absolute prerequisite for unity to be established, and given that there does not appear to be any other technical feature common to the claimed subject matter as a whole which might be able to fulfill this role, the currently claimed subject matter lacks unity of invention according to Rule 13.1 PCT.

Consequently, the claimed subject matter is restricted into the above Groups of Inventions for the following reasons.

A rat embryonic stem cell of Group I, a culture medium of Group IV, a differentiated cell of Group VI, a cDNA library or a genomic library or a cell extract of Group VII, a genetically modified rat of Group X are different compositions that are different structurally and chemically and they do not have the same properties one from the others. The methods in Groups II-III, V, VIII and IX are drawn to different methods having different starting materials, different method steps and different desired end-results. For example, the method of Group II is directed to a method producing a rat embryonic stem cell with the specific steps recited in claim 8, the subculture method of Group III does not even require the use of rat embryonic stem cells prepared by the method in Group II, the method of Group V is directed to a differentiation method, the method of Group VIII is drawn to a screening method and the method of Group IX is directed to a method for producing a genetically modified rat.

Although the rat embryonic stem cell of Group I and the method of Group II are related as process of making and product made, it should be noted that the rat embryonic stem cell can be prepared by a different process other than the method of Group II, for example by the method taught at least by Loring (US 2002/0188963; IDS).

Similarly, a differentiated cell of Group VI and the differentiated method in Group V or a genetically modified rat of Group X and the method for producing a genetically modified rat of Group IX are related as process of making and product made, however, it is noted that the differentiated cell of Group VI or the genetically modified rat of Group X can be made by methods other than those of Group V and IX, respectively; for example generating a genetically modified rat via a genetically modified fertilized rat egg and differentiated rat cells derived thereof.

Inventions I and V, VII, IX are related as product and process of use. In the instant case the rat embryonic stem cell of Group I can be used in any one of the methods of Groups V (a differentiation method), VII (screening method) and IX (making a genetically modified rat).

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Species restriction:

Should Applicants elect Group X, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(a) chimeric rat; (b) knockout rat; (c) knockin rat; (d) transgenic rat and (e) knockdown rat.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each of the aforementioned genetically modified rat species is different structurally and has different properties one from the others. Each different structure can be considered to be a "special technical feature"; and therefore the listed species lack the same or corresponding special technical features.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/QUANG NGUYEN/

Primary Examiner, Art Unit 1633